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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service d1552b

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-35

March 5, 1998

Mr. James J. Dusek
Vice President
All Care USA Medical Specialties
1001 West Commercial Boulevard
Fort Lauderdale, Florida 33309

Dear Mr. Dusek:

Inspection of your medical gas filling operation on February 4 & 5, 1998, by FDA Investigator Jennifer M. Donzanti, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen received to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not adequately tested for purity and identity prior to release for distribution. Testing is inadequate in that no documentation is available to show that at least one filled cylinder from each uninterrupted filling sequence is tested for purity and identity, and there is no documentation available to show that the [redacted] oxygen analyzer used by your firm is properly calibrated prior to use in accordance with instructions from the manufacturer.

Established written procedures for production and process controls designed to assure that you medical oxygen products have the identity, strength, quality, and purity they are

represented to possess are not being followed. Batch production and control records are not maintained documenting that each significant step in the manufacturing operation was accomplished, such as all required pre and post fill cylinder inspections and testing of finished product. Records documenting calibration and maintenance of equipment are not maintained.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations, including examples of any documentation showing that corrective action has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Douglas D. Tolen
Director, Florida District